4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0414]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0601. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Manufactured Food Regulatory Program Standards

OMB Control Number 0910-0601--Revision

This information collection supports the FDA's "Manufactured Food Regulatory Program Standards" (2019) (https://www.fda.gov/media/131392/download). We recommend that States use these program standards as the framework to design and manage their manufactured food programs. There are 44 State programs enrolled in the Manufactured Food Regulatory Program Standards (MFRPS or the program standards) under cooperative agreements.

The goal of the MFRPS is to implement a nationally integrated, risk-based, food safety system focused on protecting public health. The MFRPS establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of manufactured food regulatory programs in the United States. The development and implementation of the standards will help Federal and State programs better direct their regulatory activities toward reducing foodborne illness. For more information, and to access the program standards, we invite you to visit our website at: https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/regulatory-program-standards/manufactured-food-regulatory-program-standards-mfrps.

FDA recommends that a State program enrolled in the MFRPS use the worksheets and forms contained in the standards; however, alternate forms that are equivalent may be used. The State program maintains documentation (guidance, procedures, documents, and forms) required by the 10 standards, which must be current and fit for use. In the first year of implementing the program standards, the State program conducts a baseline self-assessment of the documentation to determine if it meets the elements of each standard. The State program must participate in additional verification audits in subsequent years. After 5 years, FDA will conduct a comprehensive program audit of the documentation. As part of the program audit, the auditor reviews the records and supporting documents required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program's

level of conformance with each of the standards. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) the individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

In the *Federal Register* of January 13, 2022 (87 FR 2162), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Subsequent to the publication of the 60-day notice, in collaboration with the State Governments, FDA completed a revision of the program standards. In an effort to improve program effectiveness, understanding and clarity, changes include those to program definitions, inspection procedures, appendices and assessment worksheets that may be used by the States who have adopted the MFRPS. A copy of the revised program standards is available in the docket.

The revised program standards are the result of external collaboration and coordination between FDA and the Association of Food and Drug Officials Manufactured Food Regulatory Program Alliance and the Partnership for Food Protection Governing Council. We consider any formal comments received on the previous edition of the program standards and feedback obtained from our collaboration with the States.

Description of Respondents: Respondents are State Departments of Agriculture or Health enrolled in the MFRPS (State Governments).

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Type of Respondent; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Governments; Development and reporting of data consistent with MFRPS	44	1	44	569	25,036

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Type of Respondent; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State Governments; Maintenance of data records consistent with MFRPS	44	10	440	40	17,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted the number of respondents to the information collection to reflect the enrollment of an additional State since our last evaluation.

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-15737 Filed: 7/21/2022 8:45 am; Publication Date: 7/22/2022]